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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/635,679	08/10/2000	Joel F. Habener	0609.1090009/MAC	6862

26111 7590 05/23/2003

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EXAMINER

MINNIFIELD, NITA M

ART UNIT PAPER NUMBER

1645

DATE MAILED: 05/23/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/635,679

Applicant(s)

HABENER, JOEL F.

Examiner

N. M. Minnifield

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2003 and 05 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-28 is/are pending in the application.
- 4a) Of the above claim(s) 20-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Response to Amendment

1. Applicant's amendments filed February 27, 2003 and March 5, 2003 are acknowledged and have been entered. Claims 15-19 are now pending in the present application. All rejections have been withdrawn in view of Applicant's comments with the exception of those discussed below.
2. This application contains claims 20-28 are drawn to an invention nonelected with traverse in Paper No. 13. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 15 and 16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 5 and 7 of U.S. Patent No. 5120712. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim of derivative of GLP-1 (7-37); wherein said derivative has an insulintropic activity that exceeds the insulintropic activity of GLP-1 (1-37) and GLP-1 (1-36).

5. Claims 15-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Mojsov NIH Grant Application, 1987.

It is noted that the previous anticipation rejection was set forth under 102(a). However, upon review of the parent applications, it appears that the effective filing date should be 6/1/90, the filing date of the last continuation-in-part. Therefore the Mojsov NIH Grant Application, 19987 would be an anticipation rejection under 102(b) rather than 102(a). If Applicant wishes to provide evidence to the contrary the Examiner will consider such evidence.

Mojsov NIH Grant Application 1987 discloses derivatives of GLP-1 (7-37) (p. 13; p. 16). Mojsov discloses the synthesis of analogs of GLP-1 (7-37) (p. 24-27) and assaying these analogs for insulinotropic activity (p. 27-28).

The derivatives appear to be the same. Since the Patent Office does not have the facilities for examining and comparing applicants' derivative with the derivative of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed derivative and the derivative of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

The rejection is maintained for the reasons of record. Applicant's arguments filed February 27, 2003 have been fully considered but they are not persuasive. It is noted that Applicant respectfully requests that this rejection be held in abeyance pending completion of an inventorship determination as discussed below in the section addressing the rejection under 35 USC 102(f).

6. Claims 15-19 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

The prior art of Mojsov NIH Grant Application provided by Applicant indicates that Applicant is not the sole inventor of the claimed invention. Mojsov is listed as the principal investigator on the NIH Grant Proposal, but Mojsov is not listed as an inventor in the pending patent application.


The rejection is maintained for the reasons of record. Applicant's arguments filed February 27, 2003 have been fully considered but they are not persuasive. Applicant asserts that Mojsov does not raise a presumption that Dr.

Mojsov is an inventor or co-inventor of the subject matter as claimed, but that an inventorship determination is being conducted. It is noted that Applicant respectfully requests that this rejection be held in abeyance until such time that the inventorship investigation is complete.

7. No claims are allowed.
8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 703-305-3394. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 703-308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


NITA MINNIFIELD
PRIMARY EXAMINER
AU 1645
5/8/03